

Study Protocol

The structural and organisational impacts of perioperative enhanced care services in the UK: A Retrospective Evaluation of Post-operative Alternatives to Critical Care (REPACC)

Pan-London Perioperative Audit & Research Network

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Correspondence

Chief Investigator (CI):

Dr Christopher Oddy

Department of Anaesthesia

Kingston Hospital

Galsworthy Rd

Kingston upon Thames


KT2 7QB

Email: repacc.plan@gmail.com

Signature Page and Statement

The chief investigator (CI) and Research and Development Department have discussed this protocol. The investigators agree to perform the investigations and to abide by this protocol.

The Investigator agrees to conduct the trial in compliance with the protocol, good clinical practice (GCP), the Data Protection Act (2018), the Trust Information Governance Policy (or other local equivalent), the Research Governance Framework (2005), the sponsor's standard operating procedure (SOP), and other regulatory requirements as appropriate.

Chief Investigator	Signature: 	Date: 05/02/23
Dr Christopher Oddy – Anaesthetics Trainee Department of Anaesthesia Kingston Hospital Galsworthy Rd Kingston upon Thames, KT2 7QB Tel: 07774 364 202 Email: chris.oddy@nhs.net		
Sponsor Representatives	Signature:	Date:
Mr Thomas Lafferty – Deputy Chief Executive Research and Innovation Department 5th Floor Surgical Centre Kingston Hospital Galsworthy Rd Kingston upon Thames, KT2 7QB Email: khft.researchgovernance@nhs.net		



<p>Janice Sorrell – Information Governance Lead</p> <p>Kingston Hospital Galsworthy Rd Kingston upon Thames, KT2 7QB</p> <p>Email: janice.sorrell@nhs.net</p>	<p>Signature:</p>	<p>Date:</p>
<p>William Oldfield – Caldicott Guardian</p> <p>Kingston Hospital Galsworthy Rd Kingston upon Thames, KT2 7QB</p> <p>Email: william.oldfield1@nhs.net</p>	<p>Signature:</p>	<p>Date:</p>

List of abbreviations

CI	Chief Investigator
CRF	Case Report Form
EPR	Electronic Patient Record
GCP	Good Clinical Practice
HDU	High Dependency Unit
ICU	Intensive Care Unit
ID	Identification Number
OIR	Overnight Intensive Recovery
OR	Odds Ratio
PACU	Post Anaesthetic Care Unit
PLAN	Pan-London Perioperative Audit & Research Network
SOP	Standard Operating Procedure
SMG	Study Management Group
TRN	Trainee Research Network

Key words: perioperative care, enhanced recovery, enhanced care, cancellation, post-anaesthetic care unit, overnight intensive recovery, intensive care, high dependency, model of care

Study synopsis

Study title:	The structural and organisational impacts of perioperative enhanced care services in the UK: A Retrospective Evaluation of Post-operative Alternatives to Critical Care (REPACC)
Study drug(s):	Not applicable.
Chief investigator:	Dr Christopher Oddy.
Condition/disease under investigation:	High risk elective surgeries.
Study duration:	Estimated 9 months.
Clinical phase:	Not applicable.
Study objectives:	<ul style="list-style-type: none"> • To describe the current models of enhanced care operational within the UK. • To identify the structural and organisational factors associated with rate of on-the-day cancellation due to lack of an enhanced care bed space. • To evaluate the effect of different models of enhanced care on wider measures of organisational efficiency.
Study population:	Adult patients undergoing elective surgery, excluding cardiothoracic and neurosurgery, who were pre-operatively referred for an enhanced care bed.
Methodology:	Multicentre retrospective service appraisal.
Eligibility criteria:	<p>Inclusion criteria Participants will be included if they meet the following criteria:</p> <ul style="list-style-type: none"> • Aged 18 years or older. • Undergoing elective or expedited surgery (NCEPOD 3 and 4) between 01/09/23 and 30/11/23. • Referred for a post-operative enhanced care bed. • Decision made to refer for an enhanced care was made before the scheduled time of the procedure.

	<p>Exclusion criteria</p> <p>Participants will be excluded if they meet the following criteria:</p> <ul style="list-style-type: none">• Undergoing emergency surgery (NCEPOD 1 and 2, or Unclassified).• Referred for an enhanced care bed intra-operatively or post-operatively.• Undergoing obstetric, cardiothoracic or neurosurgery.• Died intra-operatively.• Receiving surgery for the purpose of organ donation.
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Study background

Delivery of post-operative critical care for high-risk surgical patients represents a significant challenge within the NHS due in part to high bed occupancy rates [1]. Rates of on-the-day cancellation of elective procedures, and deferral of treatment until outside of the recommended 28-day window post-cancellation, due to absence of an appropriate post-operative destination are high, at a time when surgical waiting list pressures are at unprecedented levels [2-3].

The requirement for a post-operative critical care bed is independently predictive of on-the-day cancellation of elective surgery in the UK [4]. In order to reduce unnecessary cancellation, and relieve pressure on critical care beds, new models of care such as Post-Anaesthetic Care (PACU) and Overnight Intensive Recovery (OIR) units have evolved [5-6].

The faculty of intensive care medicine has advocated for funding of these facilities, collating an evidence base comprised of a heterogeneous sample of facilities whose introduction have led, in single centre cohorts, to improvements in organisational efficiency and certain clinical outcomes [7-8]. In 2019, approximately 55% of surveyed organisations in the UK had some form of intermediate enhanced care facility, such as PACU or OIR, for the care of high-risk post-operative patients [9]. These were predominantly anaesthetist led, caring for a median of 4 patients, with just less than 30% of institutions having ring-fenced bedspaces for this purpose.

Whilst intuitively these models of care stand to improve organisational efficiency, there is speculation that reduced clinical and risk score thresholds for admission to these intermediate units may serve to increase the likelihood of on-the-day cancellation if these services are over-burdened. The finding that institutions with an operational PACU or OIR demonstrate significantly higher rates of on-the-day cancellation adds weight to this concern [4].

Presently, there are no resources that describe the current status of enhanced care services operational within the UK. It is therefore unknown whether the recommendations made by the faculty of intensive care medicine in 2020, concerning the development of enhanced care services, have been followed [10]. Furthermore, whilst these models of care are increasingly prevalent [5], there is a paucity of literature addressing the organisational impacts of their introduction, or indeed which models of care are most effective in reducing systemic pressure.

Study design

This is a multicentre research project comprised of 2 components:

1. A retrospective analysis of on-the-day cancellation rates, and several other measures of organisational efficiency, in patients referred to enhanced care facilities for post-operative care between 01/09/23 and 30/11/23.
2. A qualitative appraisal of the structure of enhanced care services at participating centres.

Recruitment of participating centres will be conducted through regional trainee research networks (TRNs). TRN committee members will identify local investigators to set up study activities at each site using guidance documents provided by the study management group (SMG). These sites, each with differing models of enhanced care, will be compared according to several care quality indices.

Objectives

1. To describe the current models of enhanced care operational within the UK.
2. To identify the structural and organisational factors associated with rate of on-the-day cancellation due to lack of an enhanced care bed space.
3. To evaluate the effect of different models of enhanced care on wider measures of organisational efficiency.

Eligibility criteria

Inclusion criteria

Participants will be included if they meet the following criteria:

- Aged 18 years or older.
- Undergoing elective or expedited surgery (NCEPOD 3 and 4) [11] between 01/09/23 and 30/11/23.
- Referred for a post-operative enhanced care bed.
- Decision made to refer for an enhanced care was made before the scheduled time of the procedure.

Exclusion criteria

Participants will be excluded if they meet the following criteria:

- Undergoing emergency surgery (NCEPOD 1 and 2, or Unclassified) [11].
- Referred for an enhanced care bed intra-operatively or post-operatively.
- Undergoing obstetric, cardiothoracic or neurosurgery.

- Died intra-operatively.
- Receiving surgery for the purpose of organ donation.

Study procedure and assessments

Cohort identification

A step-by-step description of our cohort identification and data collection process can be found in the document entitled “Site Setup Guide”.

Our cohort will be comprised of adult patients undergoing elective surgery who were pre-operatively referred for an enhanced care bed. Enhanced care beds were defined as within high dependency, intensive care, and PACU/OIRs, or facilities specifically designed to accommodate high risk post-operative patients requiring internal referral for admission.

Participants will be primarily identified at each site through records of referral pathways to enhanced care services. These records may include secure email inboxes, locally designed databases, and electronic patient record (EPR) data. Once participant data is collated our population will be possible to divide into 6 distinct groups that will be the subject of our analysis:

1. Patients who were cancelled due to a lack of enhanced care bed. [On-target cancellations]
2. Patients who were cancelled for another reason. [Off-target cancellations]
3. Patients who had their operation and were admitted post-operatively to an enhanced care facility of any type, which will include:
 - a. Patients who were admitted to the planned level of enhanced care bed post-operatively. [As planned]
 - b. Patients who were admitted to a higher level of enhanced care bed post-operatively. [Escalations]
 - c. Patients who were admitted to a lower level of enhanced care bed post-operatively. [De-escalations]
4. Patients who had their operation and were **not** admitted post-operatively to an enhanced care facility. [Ward de-escalations]

It is likely that the referral process in many institutions will rely, at least partially, upon verbal on-the-day handover and will therefore not be identified by the methods above. The cohort of patients referred in this manner will be important to capture as the likelihood of cancellation in this group may be greater due to difficulty matching the number of daily referrals to the available resources. Identification of this cohort may be possible by combining 2 methods.

Step 1 ([On-target cancellations], [Off-target cancellations]):

1. Identify patients who were cancelled on-the-day through coding data.
2. Examine the reason for this for each person:
 - a. Many will already be coded as “critical care bed unavailable” or similar and can be automatically included [On-target cancellations].
 - b. Some will have been cancelled due to a lack of enhanced care bed but will not be coded as such [On-target cancellations].
 - c. Others will have been referred for enhanced care but were cancelled for other reasons [Off-target cancellations].
3. Exclude those that were not referred for a post-operative enhanced care bed to retain on and off target cancellations in those that were referred.

Step 2 ([As planned], [Escalations], [De-escalations]):

1. Identify a list of patients coded as admitted to enhanced care facilities post-operatively.
2. Compare this list to the list of patients formally referred for enhanced care by other means and remove duplicates – this should also identify all of the patients that were formally referred.
3. Exclude emergency admissions from the discovered cohort by reading individual patient notes.

This approach will capture all of our study groups apart from [Ward de-escalations]. Such patients are unlikely to have a traceable record of pre-operative referral and cannot be identified, as for [As planned], [Escalations] and [De-escalations], by admission to enhanced care post-operatively. Whilst this cohort is likely to represent a minority of patients, failure to capture these patients will be acknowledged as a limitation in our final publication.

Data collection

A step-by-step description of our cohort identification and data collection process at each site can be found in the document entitled “Site Setup Guide”. This document specifies how we will approach excluding participants who have opted out of their data being used for research purposes.

Patient level data

Our analysis firstly aims to capture the proportion of patients that have their elective surgical procedure cancelled due to absence of a post-operative enhanced care bed at each site. We aim to further characterise the delivery of enhanced care services at participating organisations by examining per-patient escalation and de-escalation of post-operative destination, emergency admission to critical care in the peri-operative

period, length of stay, and mortality. Data will be collected for eligible participants within the study period pertaining to:

- Patient demographics.
- Comorbidity categories derived from the Charlson Comorbidity Index.
- Planned procedure details.
- Procedure outcomes, including cancellation, emergency ICU admission, length of stay, and mortality.
- Details of cancellation if occurred.
- Reason for referral for enhanced care.
- Timing of referral to enhanced care.
- Proposed post-operative destination [12].
- Actual post-operative destination.
- Reason for escalation or de-escalation of post-operative destination.

These data will be derived from site specific referral records, clinical coding data, and EPR data.

Structure of enhanced care at participating centres

A qualitative appraisal of enhanced care services at each participating organisation will also be conducted. This will be in the form of a survey and time series of referrals and admissions to each enhanced care area during the study period. Where possible, public facing data, including hospital episode statistics (HES), situation report (SitRep), and quality outcome frameworks (QOF) data will also be collated by the SMG to add further context to our collected dataset. Data sought for analysis will include:

Organisational details

- Size, demographics, deprivation index, and disease burden of the local population.
- Size of centre.
- Presence of an emergency department.
- Surgical services available.
- Surgical waiting list size.
- Total number of operations performed on each day of the study period.
- Daily rate of on-the-day cancellation.

Process of referral to enhanced care services

- Timing of referral.
- Criteria for planned admission.
- Personnel involved in the referral process.

Resources available for enhanced care

- Presence of ring-fenced post-operative bed spaces for high-risk patients or surgeries.
- Number of ring-fenced beds available per day in each enhanced care facility.
- Number of referrals for ring-fenced beds received each day.
- Daily usage statistics for ring-fenced beds during the study period.
- Proportion of beds taken by unplanned admissions each day.
- Staffing levels of beds in each enhanced care facility.
- Consultant body responsible for supporting enhanced care in each facility.
- Consultant body responsible for discharge from enhanced care in each facility.
- Level of monitoring supported by facilities outside of ICU/HDU.
- Medical devices and therapies supported by facilities outside of ICU/HDU.

Escalation

- Escalation capacity of ring-fenced post-operative enhanced care facilities.
- Unallocated ICU/HDU capacity.

Statistical design

Investigators: Dr Christopher Oddy

Software: Python 3.11, statsmodels 0.14.0 or greater

Outcome measures

Primary outcomes

- On-the-day cancellation due to absence of a post-operative enhanced care bed.

Secondary outcomes

- Referral to capacity ratio for enhanced care services.
- Rates of escalation of post-operative destination.
- Rates of de-escalation of post-operative destination.
- Rates of emergency admission to ICU/HDU within 7 days post-operatively.
- Average length of stay in each enhanced care facility.
- Average hospital length of stay.
- Cohort mortality.

Analysis

Descriptive statistics will be generated to describe organisational and outcome parameters. Interaction terms will be calculated by multivariable linear regression to assess associations between organisational factors, cancellation rates and other outcome measures. Continuous dependent variables will be standardised to the mean before model input. Size of hospital and geographical region will be considered as grouping variables in a mixed effects model with random intercepts. Publicly available data concerning site specific total cancellation rates, critical care bed availability, operating capacity, hospital episode statistics and local population variables will contribute to model adjustment. Assumption checking will be performed to assess for normality of input variables, multicollinearity, heteroscedasticity and overall model fit by visually assessing residual versus fitted values.

Modifier variables that have a high a-priori probability of explaining variance in our outcome measures include:

- Presence of an emergency department.
- Average number of procedures performed daily.
- Proportion of total procedures performed as NCEPOD 1 and 2 [11].
- Proportion of elective procedures performed as NCEPOD 3 and 4 [11].
- Proportion of elective procedures performed for cancer.
- General & acute bed occupancy.
- Critical care bed occupancy.
- Deprivation index of local population.
- Long term condition index of local population.

These variables will be assessed for univariate association with each of our outcome measures before entry into the model. Multicollinearity is likely to be high between several of these variables. Variables with a variance inflation factor of more than 10 will be dropped systematically.

Predictor variables of interest include the following:

- Availability of level 1 care.
- Presence of ring-fenced beds.
- Number of ring-fenced beds.
- Escalation capacity.
- Referral to capacity ratio.
- On-the-day vs pre-emptive referral.
- Score vs judgement-based referral.
- Patient to provider ratio.
- Patient to provider ratio at escalation capacity.
- Therapies supported in level 1 facility.

P-values generated by the model will be used to determine the significance of each variable in modifying each outcome. Statistical significance will be defined as $p < 0.05$. Regression coefficients and odds ratios will be used to describe the relationships between predictor and outcome variables.

Sample size

We aim to analyse at least 20 institutions which will each follow up between 50-300 participants. The current scale of the project is unknown as it will depend on identifying volunteers from each site to run the data collection process.

Patient and public involvement

The study protocol has been discussed with ICUsteps, a patient led intensive care support charity, to ensure our objectives align with the priorities of service users. Suggestions made by ICUsteps members have been integrated into the protocol. They have also assisted with the creation of a plain English summary that free available online and will be distributed to all study investigators. This document also specifies how participants may withdraw their data from the study if they wish to do so.

Safety reporting

This study is purely observational, with no experimental drug or medical device being tested. There is no potential for clinical harm as a result of involvement in this study. Any adverse events observed will be as a result of the illness under observation or as a result of monitoring devices and treatments used by the clinical team. Adverse events will, therefore, not be reported to the sponsor.

Data management and quality assurance

Consent & confidentiality

All data will be handled in accordance with the Data Protection Act 2018. Data sourced from patient records at each site will be entered into the CRFs by a member of the direct care team. The proposed use of this data is to perform an evaluation of services and therefore is not considered sufficiently intrusive nor representative of sufficient risk to participants to justify seeking consent. Once participant identification is complete at each site, data will be collected for that cohort exclusively. No additional participants will be added to the cohort after this point.

The case report forms (CRFs) will be comprised of two Microsoft Excel workbooks and a survey designed in Microsoft Word. Individual patient data will be collated in the form of hospital numbers linked to generic demographic information at each site. Each subject's hospital identification numbers (IDs) will be used for identification by local investigators during the data collection process. Hospital IDs will be essential for collecting clinical data, however identifiable information linked to each number will only be accessible to members of the team directly responsible for their care. Hospital IDs will be automatically converted to study IDs by code written directly into the CRF, and only anonymised data will be shared with the SMG. It is the individual investigators' responsibility to ensure the accuracy, and responsible stewardship, of all data recorded in the CRFs before submission.

Excel based CRFs will have data validation rules and sense checking analyses built-in to ensure accurate data entry. If data is submitted in a manner that contravenes any of these checks all CRFs will be returned to local investigators for review.

Completed CRFs will be submitted to the SMG and collated into a trial master file for analysis. Data sharing with TRNs and the SMG will strictly exclude transfer of personally identifiable information including hospital IDs. Information linking study to hospital IDs will be retained by the direct care team should clarification or amendments be necessary. Information governance champions will be assigned within the SMG to ensure study procedures are followed.

Data sharing & archiving arrangements

All study documents at each site will be stored on encrypted, password-protected computer network or USB flash drives. Computer network drives (e.g. the "departmental X-drive") are an extension of the medical record systems used locally and are widely used to store patient identifiable information. USBs, if used, will be provided by local information technology departments at each site. Several encrypted copies of the study documents will be created in order to provide a back-up in the eventuality of loss of this data. Data will only be made available to study investigators or to the sponsor for study monitoring.

Data, all of which will be anonymised prior to transfer between local investigators and the SMG, will only be transferred electronically between NHS.net e-mail accounts, all of which are password protected and require multi-factor authentication. Data will only be transferred directly between local teams of investigators and the SMG at Kingston Hospital with no intermediate. Regional and organisational leads will be responsible for the secure archiving and transfer of potentially identifiable information prior to submission to the SMG in accordance with NHS Information Governance standards. The CI will be responsible for the secure archiving and stewardship of study documentation after submission to the SMG. Archiving arrangements will include the secure storage of flash drives containing study documentation by local leads and the

SMG. No external database or additional archiving systems will be utilised, as such, no funding will be sought for archiving purposes. Study documents will be kept for 10 years post-publication, after which they will be destroyed.

Termination of study activities

Anonymised data will be collated and analysed in the UK only. This will be performed by the study management group, led by the chief investigator. Data linking study and hospital IDs will be retained throughout this and the publication process. From the start of data collection, the study will run for an anticipated 12-month period, after which study activities will be terminated and local investigators will be requested to delete data linking study and hospital IDs.

Anonymised data will be retained for 10 years post-publication to permit scrutiny of our findings. These data will be stored on encrypted, password-protected computer network or USB flash drives and will only be accessible to members of the study management group unless further permissions are obtained to permit post-hoc analyses.

Direct access to source data

The investigator(s)/institution(s) will permit study-related monitoring, audits, and regulatory inspection(s), providing direct access to source data/documents.

Ethics and regulatory requirements

The protocol, and all agreed substantial protocol amendments, will be documented and submitted for ethical approval prior to implementation. Within 90 days after the end of the study, the CI and sponsor will ensure that the sponsor is notified that the study has finished. If the study is terminated prematurely, those reports will be made within 15 days after the end of the study. The CI will supply a summary report of the study to the sponsor in parallel within one year after the end of the study.

Finances

This study will receive no formal financial support.

Publication policy

Data ownership and publication rights will lie with the SMG and affiliated members of the Pan-London Perioperative Audit & Research Network (PLAN). Regional and organisational leads may use collected data for quality improvement or audit purposes, or to contribute to local research projects, provided the appropriate approvals have been granted. All local investigators will be recognised as collaborative authors on any future publications and receive a certificate acknowledging their involvement in the project that can be used to evidence research and quality improvement elements of their professional portfolio.

Statement of compliance

The study will be conducted in compliance with the protocol, sponsor's SOPs, GCP and the applicable regulatory requirement(s). This study will be conducted in compliance with the protocol approved by sponsor and according to GCP standards. No deviation from the protocol will be implemented without the prior review and approval of the sponsor. In such case, the deviation will be reported to the sponsor as soon as possible.

Committees involved in the study

Study Management Group

The SMG will be responsible for the management and monitoring of the study. The SMG will also conduct the process of data synthesis, analysis and publication. Meetings with consultant leads will be held every 1-2 months and minutes of these meetings recorded. Access to minutes will be permitted for study monitoring and regulatory inspection, or on upon reasonable request.

Regional committees

Regional committees involved will be TRNs that will be responsible for site recruitment and ensuring the protocol is followed at each site. This will entail responding to queries from sites about the conduct of the protocol at their site, and liaising with the SMG as necessary. No site data will be shared with the TRNs. Once the study period has begun, TRN meetings, where regional leads will meet with the SMG, will be held every 2 months to clarify any queries about the protocol. The full list of committees that will be involved at this stage is uncertain, currently there is anticipated involvement of:

- Pan-London Perioperative Audit & Research Network (PLAN)
- Midlands East Research by Critical Care and Anaesthetic Trainees (MERCAT)

- Welsh Anaesthetic Audit, Research & Engagement Network (WAAREN)
- Welsh Intensive Care Society Audit & Research Trainees (WICS-ART)
- South Yorkshire Hospitals Audit and Research Collaboration (SHARC)
- North West Research and Audit Group (NWRAG)

Study Personnel

Study Management Group (SMG)

Chief Investigator (CI)
<p>Dr Christopher Oddy</p> <p>Anaesthetics Trainee</p> <p>Department of Anaesthesia Kingston Hospital Galsworthy Rd Kingston upon Thames, KT2 7QB</p> <p>Tel: 07774 364 202</p> <p>Email: chris.oddy@nhs.net</p>
Consultant Leads
<p>Dr Henry Lewith</p> <p>Consultant Anaesthetist, Peri-operative Lead</p> <p>Department of Anaesthesia Kingston Hospital Galsworthy Rd Kingston upon Thames, KT2 7QB</p> <p>Email: henrylewith@nhs.net</p>
<p>Dr Paolo Perella</p> <p>Consultant Anaesthetist</p> <p>Department of Anaesthesia Kingston Hospital Galsworthy Rd Kingston upon Thames, KT2 7QB</p> <p>Email: paolo.parella@nhs.net</p>

<p>Dr Danny Wong</p> <p>Consultant Anaesthetist</p> <p>Department of Anaesthesia Guy's and St Thomas' NHS Foundation Trust Westminster Bridge Rd London, SE1 7EH</p> <p>Email: danny.wong@gstt.nhs.uk</p>
<p>Trainee Members</p>
<p>Dr Mark Burnett</p> <p>Anaesthetics Trainee</p> <p>Department of Anaesthesia Queen's Hospital Burton Belvedere Road Burton on Trent Staffordshire, DE13 0RB</p> <p>Email: burnettmark01@gmail.com</p>
<p>Dr Sarah Towey</p> <p>Anaesthetics Trainee</p> <p>Department of Anaesthesia Queen's Medical Centre Derby Rd, Lenton Nottingham, NG7 2UH</p> <p>Email: sarahtowey.st@gmail.com</p>
<p>Dr Thomas Davies</p> <p>Anaesthetics Registrar and NIHR Academic Clinical Fellow</p> <p>Department of Anaesthesia Barts and the London School of Anaesthesia Queen Mary University of London Charterhouse Square London, EC1M 6BQ</p> <p>Email: thomas.davies6@nhs.net</p>
<p>Dr Adam Green</p> <p>Anaesthetics Registrar</p> <p>Department of Anaesthesia St George's Hospital</p>

<p>Blackshaw Rd London, SW17 0QT</p> <p>Email: adam.green2@nhs.net</p>
<p>Dr Olivia Bools</p> <p>Foundation Trainee</p> <p>Department of Anaesthesia Kingston Hospital Galsworthy Rd Kingston upon Thames, KT2 7QB</p> <p>Email: o.bools@nhs.net</p>
<p>Dr Joseph Kennedy</p> <p>Acute Care Common Stem Trainee</p> <p>Department of Emergency Medicine Kingston Hospital Galsworthy Rd Kingston upon Thames, KT2 7QB</p> <p>Email: joseph.kennedy3@nhs.net</p>
<p>Dr Dominic Lowcock</p> <p>Anaesthetics Trainee</p> <p>Department of Anaesthesia Kingston Hospital Galsworthy Rd Kingston upon Thames, KT2 7QB</p> <p>Email: dominic.lowcock@nhs.net</p>
<p>Dr Gareth Davey</p> <p>Anaesthetics Trainee</p> <p>Department of Anaesthesia Kingston Hospital Galsworthy Rd Kingston upon Thames, KT2 7QB</p> <p>Email: gareth.davey1@nhs.net</p>

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